K000666

OCT 13 2000

510(k) Summary of Safety and Effectiveness

August 24, 2000

Contact: Hartmut Loch, C.E.O.
PLUS ORTHOPEDICS
3550 General Atomics Court, Bldg. 15-100
San Diego, CA 92121

Trade name: TC-PLUS™ Solution Knee

Common name: Knee Joint Prosthesis

Classification name: Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer

Equivalence: Encore Foundation Knee System (K923277, SE date 02/09/93)

Characteristics: The TC-PLUS™ Solution is a tri-compartmental total knee prosthesis comprised of femoral, patellar and tibial components with an intrinsic tibial PE-insert. Standard, Posterior Stabilized (PS) and Ultra-Congruent components are available. The PS is available for indications requiring greater stability and the Ultracongruent option may be used as an alternative for increasing A/P stability.

Indications: The TC-PLUS™™ Solution Knee is intended as a cemented surface replacement in treating patients who are candidates for primary total knee arthroplasty or revision knee arthroplasty. It is indicated for degenerative, post-traumatic or rheumatoid arthritis, avascular necrosis of the femoral condyle, post-traumatic loss of joint configuration, in particular in the event of patello-femoral erosion, functional disability or an earlier patellectomy; moderate varus, valgus or flexure deformity and to correct earlier unsuccessful attempts at surgery.

Contraindications: Contraindications include acute or chronic infections (local or systemic) or a history of infection; severe muscular, neurological, or vascular deficiencies which compromise the affected extremity; bone defects or insufficient bone quality which may affect the stability of the implant; any concomitant illness which may compromise the function of the implant; severe obesity; allergy to the implant materials; subluxation of the femur against the eminentia; ligament instability; severe varus or valgus misalignment; retropatellar degenerative arthritis; extension contractures over 10°.

Performance data: Biomechanical Testing has been provided. All test results are sufficient for *in vivo* loading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 13 2000

Mr. Hartmut Loch
Chief Executive Officer
PLUS Orthopedics
3550 General Atomics Court
Building 15-100
San Diego, California 92121-1122

Re: K000666
Trade Name: TC–PLUS Solution Knee
Regulatory Class: II
Product Code: JWH
Dated: August 24, 2000
Received: August 25, 2000

Dear Mr. Loch:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000666

Device Name: TC-PLUS™ Solution Knee

Indications for Use:

The TC-PLUS™™ Solution Knee is intended as a cemented surface replacement in treating patients who are candidates for primary total knee arthroplasty or revision knee arthroplasty. It is indicated for degenerative, post-traumatic or rheumatoid arthritis, avascular necrosis of the femoral condyle, post-traumatic loss of joint configuration, in particular in the event of patello-femoral erosion, functional disability or an earlier patellectomy; moderate varus, valgus or flexure deformity and to correct earlier unsuccessful attempts at surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE –CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhauser

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000666

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use ____

(Optional Format 1-2-96)